Senate Bill No. 1606

CHAPTER 778

An act to amend Section 1261.5 of, and to add Section 1261.6 to, the Health and Safety Code, relating to health facilities.

[Approved by Governor September 22, 1998. Filed with Secretary of State September 23, 1998.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1606, Lewis. Pharmacy: automated drug delivery systems.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy, under the jurisdiction of the California State Board of Pharmacy. It prescribes requirements for the dispensing of drugs, as specified.

Existing law provides for the licensing and regulation of health facilities, including skilled nursing facilities and intermediate care facilities, administered by the State Department of Health Services.

Existing law limits the number of oral dosage form or suppository form drugs provided by a pharmacy to a skilled nursing facility or intermediate care facility for storage in a secured emergency supplies container to 24 and authorizes the department to provide for other specified limitations.

This bill would provide, commencing July 1, 1999, that limitations imposed pursuant to these provisions on the number or quantity of oral or suppository form drugs provided by a pharmacy to a skilled nursing or intermediate care facility shall not apply to an automated drug delivery system, as defined by the bill, when a pharmacist controls access to the drugs.

The bill would also provide, commencing July 1, 1999, that access to an automated drug delivery system shall be limited to personnel authorized by law to administer drugs and who have an access code to these systems, would set forth requirements of a health facility and pharmacy with regard to the installation, operation, and review of an automated drug delivery system, and would exempt an automated drug delivery system from certain drug labeling requirements.

The people of the State of California do enact as follows:

SECTION 1. Section 1261.5 of the Health and Safety Code is amended to read:

1261.5. (a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4035

of the Business and Professions Code, shall be limited to 24. The State Department of Health Services may limit the number of doses of each drug available to not more than four doses of any separate drug dosage form in each emergency supply.

(b) Any limitations established pursuant to subdivision (a) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d) of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs. This subdivision shall become operative July 1, 1999.

SEC. 2. Section 1261.6 is added to the Health and Safety Code, to read:

1261.6. (a) For purposes of this section and Section 1261.5, an ''automated drug delivery system'' means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the location where the automated drug delivery system is being used.

(e) Drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by, an intern pharmacist, or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(g) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review, which shall be conducted on a monthly basis, by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(h) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

(h) This section shall become operative July 1, 1999.

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